K050225

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510(k) Summary

January 31, 2005

Submitter: Cambridge Heart, Inc
1 Oak Park
Bedford, Ma 01730
(781) 271-1200
(781) 275-8431

Contact: Dave Chazanovitz

510(k) Numbers and Product Codes of equivalent devices:

Cambridge Heart, Inc.; HearTwave II Cardiac Diagnostic System

510(k) Number: # K022149

Product Code: 74 DPS

CFR Section: 870.2340

Indications for Use and Intended Population

The HearTwave II Cardiac Diagnostic System is intended for the recording of electrocardiograms, vector cardiograms and measurement of Microvolt T-Wave Alternans* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the analytic spectral method of the HearTwave II Cardiac Diagnostic System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Cambridge Heart HearTwave II Cardiac Diagnostic System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

Device Description

The Cambridge Heart HearTwave II Cardiac Diagnostic System is intended for the measurement and recording of T-Wave alternans. The alternans levels reported in K983012, K001034, K003492 and K022149 were measured using the Analytic Spectral Method. This method consists of several computational steps that combine to form a

unique analytical process. The Microvolt T-wave Alternans measurement, the output of this specific process, has been shown to be useful in predicting ventricular tachyarrhythmias and sudden cardiac death.

The Cambridge Heart HearTwave II Cardiac Diagnostic System provides T-wave alternans diagnostic capabilities to standard stress labs. The Analytic Spectral Method of Alternans Processing used in the Cambridge Heart HearTwave II is intended for the measurement of microvolt T-Wave alternans at rest and during treadmill, ergometer and pharmacologic stress testing.

The Alternans test using the Cambridge Heart HearTwave II is performed with seven standard stress test electrodes and seven proprietary multi-segment Micro-V Alternans™ Sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn Patient module, which provides digitized data to the HearTwave II.

Patient Electrodes:

Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Cambridge Heart Model HearTwave II Cardiac Diagnostic System.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res Electrode (Ref: # K962115) or The Cambridge Heart Micro-V Alternans Sensor (Ref: #K002230) in conjunction with other Patient electrodes designed and approved specifically for use during exercise stress testing.

Performance Standards

The Cambridge Heart HeartWave II Cardiac Diagnostic System is designed to meet the following Performance Standards:

- ANSI/AAMI EC11-1991
- EN60601-1: 2004, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments A1 and A2
- EN60601-1-1: 2000, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Collateral standard: Safety requirements for medical electrical systems"
- EN60601-1-2: 2004, "Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"
- EN60601-1-4: 2000, "Medical Electrical Equipment, Programmable Medical Systems"
- IEC 60601-2-25: 1993, "Particular requirements for the safety of electrocardiographs" including Amendment 1
- IEC 60601-2-51: 2003 "Particular requirements for safety, including essential performance, of recording and analyzing single and multichannel electrocardiographs

- FDA Diagnostic ECG Guidance: 1998, Version 1.0
- FDA Electrocardiograph Lead Switching Adaptor Guidance: 1997, Version 1.0
- FDA Guidance For Industry: 2000 " General Principles of Software Validation"
- FDA Guidance For Industry: 1999 " Guidance for Off-The –Shelf Software for use in Medical Devices"
- ISO 14971: 2000 " Application of risk management to medical devices"

Similarities and Differences to Predicates

The Model HearTwave II Cardiac Diagnostic System (new) is essentially the same device as in K02149 with the exception of the modification described in this pre-market submission. The Model HearTwave II Cardiac Diagnostic System uses the same Analytic Spectral Method as the CH2000 (K02149) for measuring T-Wave Alternans.

Conclusion

There are more similarities than differences between the predicate device and the Cambridge Heart HearTwave II Cardiac Diagnostic System. Both the predicate devices use the Analytic Spectral Method of Alternans Processing. When used in accordance with the directions for use, by qualified personnel, the Cambridge Heart HeartWave II Cardiac Diagnostic System is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Cambridge Heart, Inc.
c/o Mr. John Greenbaum
20310 SW 48th Street
Ft. Lauderdale, Florida 33332

Re: K050225
Trade Name: HearTwave II Cardiac Diagnostic System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: 74 DQK
Dated: March 11, 2005
Received: March 15, 2005

Dear Mr. Greenbaum:

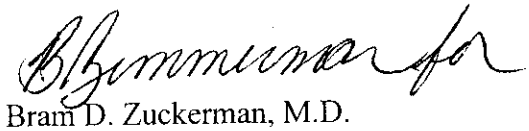
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K050225

Device Name: HearTwave II Cardiac Diagnostic System

Indications For Use:

The HearTwave II Cardiac Diagnostic System is intended for the recording of electrocardiograms, vector cardiograms and measurement of Microvolt T-Wave Alternans* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the HearTwave II Cardiac Diagnostic System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The HearTwave II Cardiac Diagnostic System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests. The interpretive results of the Alternans Processing System should be reviewed by a qualified physician.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050225